IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

VEECH, Richard L.

Atty. Ref.: 604-591

Serial No. Unassigned

Group:

Filed: April 30, 2001

Examiner:

For: THERAPEUTIC COMPOSITIONS

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April 30, 2001

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

PRELIMINARY AMENDMENT

Please amend the above application as follows:

IN THE CLAIMS

Please substitute the following amended claims for corresponding claims previously presented. A copy of the amended claims showing current revisions is attached.

5. (Amended) A method as claimed in Claim 1 wherein on administration of the compound to an unfasted patient in need of such therapy,

the blood level of ketone bodies, defined as the sum total of D-β-hydroxybutyric acid and acetoacetate, is raised to between 0.3 and 20mM.

6. (Amended) A method as claimed in Claim 1 wherein the neurodegenerative disorder is selected from the group consisting of neurodegenerative disorders involving inability to metabolise glucose, memory loss in ageing, neurotoxic peptides or proteins, and genetic abnormality.

8. (Amended) A method as claimed in Claim 1 wherein the metabolic precursor is selected from the group consisting of Free Fatty Acids and compounds comprising 1,3-butandiol, acetoacetyl or D-β-hydroxybutyryl moieties.

9. (Amended) A method as claimed in Claim 1, wherein the metabolic precursor is a polymer or oligomer of D-β-hydroxybutyrate.

14. (Amended) A method as claimed in Claim 1, wherein the level of ketone bodies produced in the blood is in the ratio 1:1 to 20:1 of D-β-hydroxybutyrate to aceto acetate.

28. (Amended) Use of D-β-hydroxybutyric acid, acetoacetate, or a metabolic precursor or physiologically acceptable salt of D-β-hydroxybutyric acid or acetoacetate for the manufacture of a medicament for the treatment of a

disorder by a method as set out in Claim 1 provided that when the use is of a metabolic precursor that is not racemic hydroxybutyryl carnitine.

29. (Amended) A foodstuff as claimed in Claim 23 for use in therapy.

31. (Amended) A composition comprising a compound selected from those claimed in Claim 15 and poly D-β-hydroxybutyrate together with a physiologically acceptable carrier, in sterile and pyrogen free form.

REMARKS

The above amendments have been made to place the application in a more traditional format. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "**Version With Markings To Show Changes Made**."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

5. (Amended) A method as claimed in [any one of] Claim 1[, Claim 2, Claim 3 and Claim 4] wherein on administration of the compound to an unfasted patient in need of such therapy, the blood level of ketone bodies, defined as the sum total of D-β-hydroxybutyric acid and acetoacetate, is raised to between 0.3 and 20mM.

6. (Amended) A method as claimed in Claim 1 [or Claim 2] wherein the neurodegenerative disorder is selected from the group consisting of neurodegenerative disorders involving inability to metabolise glucose, memory loss in ageing, neurotoxic peptides or proteins, and genetic abnormality.

8. (Amended) A method as claimed in Claim 1 [or Claim 2] wherein the metabolic precursor is selected from the group consisting of Free Fatty Acids and compounds comprising 1,3-butandiol, acetoacetyl or D-β-hydroxybutyryl moieties.

9. (Amended) A method as claimed in Claim 1, [Claim 2, Claim 3 or Claim 4] wherein the metabolic precursor is a polymer or oligomer of D-β-hydroxybutyrate.

14. (Amended) A method as claimed in Claim 1, [Claim 2, Claim 3 or Claim 4] wherein the level of ketone bodies produced in the blood is in the ratio 1:1 to 20:1 of D-β-hydroxybutyrate to aceto acetate.

28. (Amended) Use of D-β-hydroxybutyric acid, acetoacetate, or a metabolic precursor or physiologically acceptable salt of D-β-hydroxybutyric acid or acetoacetate for the manufacture of a medicament for the treatment of a disorder by a method as set out in [any one of Claims 1 to 14] Claim 1 provided that when the use is of a metabolic precursor that is not racemic hydroxybutyryl carnitine.

29. (Amended) A foodstuff as claimed in Claim 23 [or Claim 24] for use in therapy.

31. (Amended) A composition comprising a compound selected from those claimed in [any one of Claims 15 to 18] Claim 15 and poly D-β-hydroxybutyrate together with a physiologically acceptable carrier, in sterile and pyrogen free form.